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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,520	04/21/2008	Theresa M. Reineke	91830.0542769	7539

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
01/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,520	REINEKE ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 2, and 4-7, drawn to double stranded concatemers containing at least two copies of sequence(s) that are repeated and act as transcription factor decoys. Election of this Group requires the further election of a single transcription factor selected from NF-κB, AP-1, ATF2, ATF3 and SP1 for reasons given below. This is not a species election.

Group 2, claim(s) 1, and 3-7 drawn to double stranded concatemers containing at least two copies of sequence(s) that are different from each other and act as transcription factor decoys. Election of this Group requires the further election of a pair of different transcription factor selected from NF-κB, AP-1, ATF2, ATF3 and SP1 for reasons given below. This is not a species election.

Group 3, claim(s) 8-10, drawn to methods of delivering transcription factor decoys in vitro or in vivo, in isolated cells or intact animals, comprising administering a concatemerized double-stranded oligonucleotide molecule at least two end-to-end repeated copies of a nueleotide sequence comprising a sequence or sequences that act as transcription factor decoys, wherein the transcription factor may be NF-κB. Election of this Group requires the further election of a physiological condition for reasons given below selected from developmental defects, aging, toxic exposure, myocardial ischemia/reperfusion and myocardial infarction, heart failure and hypertrophy, cardioprotection, stroke, neuroprotection, sepsis, arthritis, asthma, heritable inflammatory disorders, cancer, heritable immune dysfunctions, inflammatory processes caused by disease, inflammatory processes caused by injury, inflammatory processes caused by infection, oxidative stress caused by disease, oxidative stress caused by surgery, oxidative stress caused by injury, oxidative stress caused by response to surgery, or oxidative stress caused by response to trauma. This is not a species election.

Group 4, claim(s) 11-29, drawn to a method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a polynucleotide NF-κB chromosomal binding site decoy which antagonizes NF-κB-mediated transcription of a gene located downstream of a NF-κB binding site wherein the polynucleotide comprises one or more copy of the oligonucleotide decoy . Election of this Group requires the further election of a single physiological condition for reasons given below selected from a reperfusion disorder in

ischemic disease, aggravation of a prognosis of an organ or aggravation of a prognosis of a heart transplantation or aggravation of a prognosis of an organ surgery, a post-PTCA restinosis, an inflammatory disease, an autoimmune disease, a cancer metastasis, a cancer invasion, cachexia, an immunological disorder, septic shock, transplant rejection, radiation damage, a reperfusion injury after ischemia, arteriosclerosis, a neurodegenerative disease, inhibition of cell death and apoptosis in ischemic-reperfused myocardium, inhibition of cell death and apoptosis in ischemia ischemic-reperfused brain, inhibition of apoptosis in congestive heart failure inhibition of apoptosis in cardiomyopathy, or procedural vascular trauma. This is not a species election.

Groups 1 and 4 lack unity. Although both require the same special technical feature of an NF-κB decoy, this is not considered to be a contribution over the prior art. Please see Chapter 1 search report, specifically the reference of Morishita. Morishita describe compositions comprising at least one decoy and a pharmaceutically acceptable carrier. The at least one decoy of Morishita et al. may comprise an oligonucleotide targeting NF-kB.

Groups 2 and 3 lack unity. Although both require the same special technical feature of a double stranded oligo decoy with two binding sites for two different transcription factors, this is not considered to be a contribution over the prior art. Please see Chapter 1 search report, specifically the reference of Morishita. Therein Morishita describes compositions comprising at least two decoys bonded to each other, the at least two decoys being selected from the group consisting of an NF-kB decoy, a STAT-I decoy, a GATA-3 decoy, a STAT-6 decoy, an AP-1 decoy and an ETS decoy.

The inventions listed as Groups 1 and 4 lack unity with Groups 2 and 3. Although both require the same special technical feature of an oligo decoy with comprising binding sites for transcription factors, this is not considered to be a contribution over the prior art for the same reasons described above.

The diseases and conditions listed above lack unity, because although all require the same special technical feature of administering an oligo decoy directed to a transcription factor to achieve amelioration of the condition, this is not considered to be a contribution over the prior art. For example, Morishita et al. teaches teach that the compositions can be used to treat inflammatory disorders such as atopic dermatitis, psoriasis, and ulcerative colitis.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/JD SCHULTZ/
Primary Examiner, Art Unit 1633